V. 510(k) Summary

Submitter

MedAmicus, Incorporated
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Date Prepared

February 15, 2002

Trade Name

MedAmicus Axia RSN™

Common Name

Catheter Introducer

Predicate Device

MedAmicus Guidewire Introducer Safety Needle, K011085
Boston Scientific Corporation Introducer Sheath and Dilator, K971165

Device Description

The MedAmicus Axia RSN™ is a single use device for percutaneous introduction of guidewires, or similar devices, up to 0.038 inches in diameter. The device is packaged as either sterile single units or as part of a kit. The device is designed with a shield as part of the safety needle mechanism to aid in the prevention of needle stick injuries. The needle of the device is retracted into the shield by pushing the button prior to removal of the device off the guidewire, or other device, and out of the body. After retraction, the shield covers the needle tip. The device is disposed of according to routine procedure in a sharps container.

Intended Use

The MedAmicus Axia RSN™ is intended to minimize needle stick injuries when used for percutaneous introduction of guidewires, or similar devices.

Technological Characteristics

The device is technologically equivalent to other introducers and safety needles. The safety feature, which forms an integral part of this device, is a retractable needle mechanism that helps to minimize the risk of needle stick injuries.

Summary of Studies

No new testing was performed for the device as the only change being made is to the Indications for Use. All testing previously summarized in K011085 remains applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2002

Mr. Dennis S. Madison
Vice President, Regulatory Affairs
MedAmicus, Inc.
15301 Highway 55 West
Minneapolis, MN 55447

Re: K020563
MedAmicus Axia RSN™
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: Class II (two)
Product Code: 74 DYB
Dated: February 18, 2002
Received: February 20, 2002

Dear Mr. Madison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VI. Indications for Use

510(k) Number (if known): Not Assigned K020563

Device Name: MedAmicus Axia RSN™

Indications for Use: The MedAmicus Axia RSN™ is intended to minimize needle stick injuries when used for percutaneous introduction of guidewires or other devices.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020563